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Washington, D.C. 20231

JUN 3 1996

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Dr. Max Fogiel
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Re: Patent Term Extension
Application for
U.S. Patent No. 4,739,101

CORRECTED NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,739,101, which claims the human drug product Lipidil®, is eligible for patent term extension under 35 U.S.C. § 156. In view of the decision of the Court of Appeals for the Federal Circuit in Merck & Co. v. Kessler, 1996 WL 156630 (1996), the period of extension has been recalculated to extend the term of the patent from its 20-year expiration date instead of the 17-year expiration date. Since the 20-year expiration date of the patent is later than the 17-year expiration date and since the 14 year limit applies, the recalculation results in a shorter extension under 35 U.S.C. § 156. The recalculated period of extension has been determined to be 248 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of August 30, 1994. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= 1/2 (\text{Testing Phase}) + \text{Approval Phase} \\ &= 1/2 (0) + (3,498 - 1,414) \\ &= 2,084 \text{ days}\end{aligned}$$

Only days of the regulatory review period occurring after the issue date of the patent may be considered in the calculation. Since the testing phase began September 6, 1981 and the approval phase began June 4, 1984, both phases of the regulatory review period began before the patent issued (April 19, 1988). Accordingly, none of the days of the testing phase and only that portion of the approval phase of the regulatory review period occurring after the patent issue date have been considered in the above determination of the length of the extension period. 35 U.S.C. § 156(c). (From June 4, 1984 to April 19, 1988 is 1,414 days; this period is subtracted for the number of days occurring in the approval phase according to the FDA determination of the length of the regulatory review period: $3,498 - 1,414 = 2,084$ days.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (December 31, 1993) when added to the period of extension calculated above (2,084 days) cannot exceed fourteen years. The period of extension is

thus limited to December 31, 2007, by operation of 35 U.S.C. § 156(c)(3). Since the original patent term would expire on April 27, 2007, twenty years after the date on which the application for the patent was filed (April 27, 1987) (35 U.S.C. § 154), the period of extension is the number of days to extend the term of the patent from its expiration date to and including December 31, 2007, or 248 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

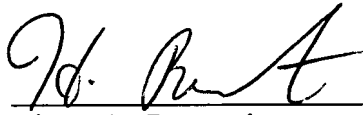
A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 248 days.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,739,101
Filed:	April 27, 1987
Granted:	April 19, 1988
Applicant:	Jean-Pierre Bourgogne et al.
Owner of Record:	Fournier Innovation et Synergie
Title:	METHOD FOR THE PREPARATION OF FIBRATES
Classification:	560/61
Product Trade Name:	Lipidil®

Term Extended:

248 days



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Senior Legal Advisor
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cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

RE: Lipidil®
FDA Docket No.: 94E-0104